IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
WESTERN DIVISION

Anthony DeGidio,

Plaintiff

v.

Centocor Ortho Biotech, Inc. *et al*,

Defendant

Case No. 3:09CV0721

ORDER

This is a product liability case. This litigation arises out of the sale of Remicade, a prescription immunosuppressant, by defendants, allegedly without adequate warning of severe side effects. Pending is defendants' motion for summary judgment. [Docs. 28, 29].

Background

Remicade is approved by the FDA for patients with severe Crohn's disease, as well as other autoimmune diseases. The drug is not a cure for Crohn's, but it may relieve symptoms. It works by rendering the patient's immune system unable to attack the body's own cells.

Plaintiff DeGidio has suffered from Crohn's disease since he was a teenager in the 1970s. He has seen gastroenterologist Dr. Slee since 1989. He received a series of four Remicade infusions between April and August 2007.

In mid-summer 2007, DeGidio developed chest burning and cough. He was given antibiotics, standard treatment for infectious pneumonia, but continued to decline.

On September 19, 2007, DeGidio was hospitalized. His condition deteriorated significantly, and he was transferred from Toledo Hospital to the University of Michigan Hospital. There doctors

continued to treat him for infectious pneumonia.

Eventually doctors from the Mayo Clinic reviewed DeGidio's lung biopsy. They diagnosed his pulmonary condition as Remicade-induced eosinophilic pneumonitis with no clear infectious etiology—referred to throughout this order as non-infectious lung disease (NILD).

After this diagnosis, the treating physicians switched DeGidio's medication from antibiotics to corticosteroids, which is the preferred treatment for non-infectious pneumonia. As a result, DeGidio improved enough to be discharged from the hospital approximately three months after first being admitted.

DeGidio alleges that Centocor failed to warn of the risk of Remicade-induced NILD. A primary issue in the summary judgment motion and at oral argument thereon is whether the Remicade label, on its face, in fact warned of the risk of Remicade-induced NILD, regardless of whether such a warning was required.

Centocor argues that because the label warns of the potential for infections and pneumonia, the label in fact warned of the non-infectious side effect experienced by DeGidio. Centocor presents no expert testimony to support this argument. Dr. Olson, DeGidio's treating pulminologist, testified that NILD is not the same as infectious-type pneumonia, and Dr. Slee testified that the label does not warn of NILD.[1]

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[1] Centocor objects to DeGidio's motion for leave to submit the testimony of Dr. Olson. [Doc. 47]. Centocor argues that the testimony does not address any disputed issue, and that the submission is unjustifiably late. The testimony does address a disputed issue: whether the specific cause of DeGidio's pneumonia is significant. Centocor claims that the causation is not significant, but has produced no medical expert testimony to support this argument. In addition, the fact that the Remicade label classifies the potential side effect of pneumonia as infectious suggests that the distinction is relevant. Dr. Olson's testimony is helpful, therefore, because it supports DeGidio's distinction between types of pneumonia. As for its lateness, the timing of the submission does not unduly prejudice Centocor, because, as Centocor notes, DeGidio "has known since the beginning of this litigation that [Centocor] would argue that the Remicade labeling is adequate due to its warning of pneumonia"—in which case Centocor has had ample

Having reviewed the affidavits and other materials offered in support of and opposing the motion and considering the arguments of counsel, I conclude that there are genuine issues of material fact involving the adequacy of the warning supplied by defendant. For now, on the narrow issue of whether the label on its face warned of Remicade-induced NILD, defendant's motion for summary judgment is denied.[2]

Discussion

I. Summary Judgment Standard

A party is entitled to summary judgment on motion under Fed. R. Civ. P. 56 where the opposing party fails to show the existence of an essential element for which that party bears the burden of proof. *Celotex Corp. v. Cartrett*, 477 U.S. 317, 322 (1986). The movant must initially show the absence of a genuine issue of material fact. *Id.* at 323.

Once the movant meets that initial burden, the "burden shifts to the nonmoving party [to] set forth specific facts showing there is a genuine issue for trial." *Anderson v. Liberty Lobby, Inc*., 477 U.S. 242, 250 (1986) (quoting Fed. R. Civ. P. 56(e)). Rule 56(e) "requires the nonmoving party to go beyond the [unverified] pleadings" and submit admissible evidence supporting its position. *Celotex, supra*, 477 U.S. at 324.

In deciding a motion for summary judgment, I accept the opponent's evidence as true and construe all evidence in the opponent's favor. *Eastman Kodak Co. v. Image Tech. Servs., Inc*., 504 U.S. 451, 456 (1992). The movant can prevail only if the materials offered in support of the motion

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opportunity to develop its arguments on this issue as well. The motion for leave to submit the testimony is granted.

[2] Whether there is enough evidence to establish a causal relationship between NILD and Remicade is not presently at issue. A warning can be inadequate, however, even where a causal relationship has not definitely been established. *See, e.g., Moran v. Johns-Manville Sales Corp.*, 691 F.2d 811, 814 (6th Cir. 1982).

show there is no genuine issue of a material fact. *Celotex*, *supra*, 477 U.S. at 323.

II. The Label

The Remicade warning effective in 2007 emphasized the danger of infections as a side-effect of taking the drug. In bold text, surrounded by a text-box, the label cautioned [Doc. 29-1]:

> **WARNINGS**
>
> **RISK OF INFECTIONS**
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> **Patients treated with REMICADE are at increased risk for infections, including progression to serious infections leading to hospitalization or death (see WARNINGS and ADVERSE REACTIONS). These infections have included bacterial sepsis, tuberculosis, invasive fungal and other opportunistic infections. Patients should be educated about the symptoms of infection, closely monitored for signs and symptoms of infection during and after treatment with REMICADE, and should have access to appropriate medical care. Patients who develop an infection should be evaluated for appropriate antimicrobial therapy and for serious infections REMICADE should be discontinued.**

The label also noted (in bold text, but not in a text-box) that:

> **WARNINGS**
>
> **RISK OF INFECTIONS**
>
> **Serious infections, including sepsis and pneumonia, have been reported in patients receiving TNF-blocking agents. Some of these infections have been fatal. Although some of the serious infections in patients treated with REMICADE have occurred in patients on concomitant immunosuppressive therapy which in addition to their underlying disease could further predispose them to infections, some patients who were hospitalized or had a fatal outcome from infection were treated with REMICADE alone.**

The Post-Marketing Adverse Events section (neither bold nor in a text box) noted the possible risk of interstitial NILD:

> The following adverse events have been reported during post-approval use of REMICADE . . . interstitial pneumonitis/fibrosis. . . . Because the events are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to REMICADE exposure.

III. Expert Testimony

A. Dr. Olson's Testimony

Dr. Olson's testimony is straightforward [Doc. 42-1]. Dr. Olson has treated DeGidio since the 2007 diagnosis of Remicade-induced eosinophilic pneumonitis with no clear infectious etiology. Dr. Olson stated "drug-induced eosinophilic pneumonitis with no clear infectious etiology is not the same as opportunistic infectious pneumonia and is considered to be non-infectious pneumonia." He explained that there are "many differences" between infectious and non-infectious pneumonias, including the way they are treated.

B. Dr. Slee's Testimony

Centocor asserts that the label warns of NILD because the label warns of pneumonia, and relies on Dr. Slee's deposition testimony. Centocor notes that Dr. Slee characterized Plaintiff's pulmonary issues as "pneumonia" because "any infiltration or any inflammatory aggregate in the lung is by definition pneumonia." [Doc. 29, at 12]. However, Dr. Slee's testimony, when considered as a whole, firmly differentiates between infectious pneumonia and NILD, and therefore should not be misconstrued as saying that the label warns of NILD. In fact, his testimony is quite the opposite.

Dr. Slee testified that pneumonia is a generic term that describes an inflammatory process in the lungs. Interstitial pneumonia means the inflammatory component is confined to the walls around the air spaces in the lungs. Eosinophilic pneumonia is a form of interstitial lung disease typically seen in allergic conditions. Dr. Slee emphasized that to say that DeGidio suffered from "pneumonia," without more, would be so imprecise as to border on incorrect. [Doc. 29-2, at 154].

In Dr. Slee's opinion, DeGidio had a "Remicade-induced non-infectious pneumonia." [Doc.

29-2, at 173]. Dr. Slee testified that the Remicade label does warn of infectious-type pneumonia.[3] [Doc. 29-2, at 196, 199]. Dr. Slee stated unambiguously, however, that the 2007 Remicade medical guide *did not* warn of a known association between the use of Remicade and the type of pneumonia from which DeGidio suffered.[4] [Doc. 29-2, at 61, 150,196, 200]. With respect to the post-market discussion, Dr. Slee agreed that the drug company was stating in the provision "that although there has been some reports post market, it cannot or has not determined whether there is, in fact, some causal relationship between Remicade and interstitial pneumonitis." [Doc. 29-2, at 196]. The label did not make Dr. Slee aware of any Remicade-induced interstitial lung disease, and does not indicate a causal relationship. [Doc. 29-2, at 59, 200, 204].

Dr. Slee's testimony is unambiguous. The Remicade label did not warn of the type of pneumonia that afflicted DeGidio.

IV. Adequacy of the Label as a Matter of Law

A threshold issue in this litigation is whether the Remicade label regarding its potential side effects adequately warned of the side effect—NILD—DeGidio suffered. The parties disagree about the adequacy of the Remicade warning, and this initial issue—whether the label did or did not warn of the side effect that the plaintiff allegedly suffered—is key for the product liability claims. Centocor alleges that the warning is adequate as a matter of law.

The Ohio Products Liability Act (OPLA) §§ 2307.71-.80 governs product liability claims brought under Ohio law. Under the OPLA, as long as adequate warning has been provided for a

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[3] Centocor points out that Dr. Slee also testified that in his opinion the warning is adequate, and that he would not differentiate between types of pneumonia in a warning to his patients. However, these issues are not in question, because if the warning as provided to the prescribing physician is inadequate, the learned intermediary doctrine does not apply.

[4] DeGidio also developed an infectious pneumonia while at the hospital being treated for non-infectious pneumonia. This is irrelevant.

drug, the manufacturer cannot be strictly liable for a design defect, regardless of whether there is a causal connection between the plaintiff's use of the drug and the plaintiff's injury or whether the product was unavoidably dangerous. *Wimbush v. Wyeth,* No. 09-3380, 2010 WL 3256029, *3 (6th Cir., Aug. 18, 2010). Under § 2307.76, a product is defective due to inadequate warning if the manufacturer: a) knew or should have known of a risk associated with the product; and b) fails to provide the warning that a manufacturer exercising reasonable care would have provided, in light of the likelihood that the product would cause the harm for which the claimant seeks to recover. As explained above, the only issue for oral argument was whether the Remicade label warned of NILD, *as a matter of law*.

Adequacy of a drug's warning label is generally a question of fact, though it can become a question of law where the warning is accurate, clear and unambiguous. *Meridia Products Liability Litigation v. Abbot Laboratories,* 447 F.3d 861, 867 (6th Cir. 2006) (quoting *Thom v. Bristol-Myers Squibb Co.*, 353 F.3d 848, 853 (10th Cir. 2003). "A warning is 'adequate' . . . where, under all the circumstances, it reasonably discloses to the medical profession all risks inherent in the use of the drug which the manufacturer knew or should have known to exist." *Saraney v. TAP Pharmaceutical Products, Inc.*, No. 4-2026, 2007 WL 148845, at *5 (N.D. Ohio, Jan. 16, 2007) (internal citations omitted). If reasonable minds can only come to one conclusion on the adequacy of the warning, when construing the evidence most strongly in favor of the non-moving party, summary judgment is appropriate.

Courts use at least five factors to determine whether a warning is adequate: 1) the warning must adequately indicate the scope of the danger; 2) the warning must reasonably communicate the extent or seriousness of the harm that could result from misuse of the drug; 3) the physical aspects of the warning must be adequate to alert a reasonably prudent person to the danger; 4) a simple

directive warning may be inadequate when it fails to indicate the consequences that might result from the failure to follow it; and 5) the means to convey the warning must be adequate. *In re Meridia Products Liability Litigation*, 328 F.Supp.2d 791, 812 (N.D. Ohio 2004).

Centocor argues that the label warned of the risks of taking Remicade (infections and pneumonia), the scope of those risks (potential death), in a physically apparent manner (black box and bold lettering). I disagree.

Centocor's contention that its label clearly and unambiguously warned of pneumonia in the broad definition of the illness is unconvincing. The heading of the black-box, bold-lettered warning is RISK OF INFECTIONS, making it a reasonable assumption that the warning refers only to infectious pneumonia. [Doc. 29-1]. Other label discussions of pneumonia and the potential for a fatal outcome similarly refer to the infectious type.[5] The conclusion that the label does not effectively communicate the risk of *non-infectious* pneumonia is bolstered by the fact that DeGidio's treating physicians struggled to identified DeGidio's illness.

The expert testimony does not contradict this conclusion. Both Drs. Slee and Olson concurred in the opinion that infectious pneumonia is distinct from NILD, and that DeGidio suffered from NILD. Dr. Slee testified further that the label did not warn of a causal relationship between Remicade and NILD. Centocor's argument that the label warns of the type of pneumonia experienced by DeGidio is therefore contradicted by Dr. Slee's testimony, and Centocor provides no other support for its argument. [Doc. 39, at 5]. DeGidio has presented a genuine issue of material fact as to whether the Remicade label warned of NILD, and therefore the label is not adequate with

[5] For example, Centocor contends that "[t]he label states that 1.7% of patients in the placebo-controlled Remicade clinical studies developed pneumonia," [Doc. 29, at 6], but that statement is in a section of the label entitled ADVERSE REACTIONS, Infections. [Doc. 29 -1, at 38] .

regard to non-infectious pneumonia as a matter of law.

Centocor also argues that it cannot be held liable for an inadequate warning because Dr. Slee, the prescribing physician, knew and understood the risks associated with Remicade use, and chose not to warn his patient of those risks. Centocor points out that Dr. Slee testified that, despite his knowledge of DeGidio's injury he would not change his prescribing behavior. Centocor's reliance on the learned intermediary doctrine is misplaced. In Ohio, a manufacturer's duty can only be discharged upon providing a learned intermediary with an adequate warning. *See, e.g., Boyd v. Lincoln Elec. Co.*, 179 Ohio App. 3d 559, 575 (2008). Whether Dr. Slee would have changed his prescribing conduct if he had received an adequate warning goes to the issue of proximate cause of DeGidio's injury—an issue which will be considered at a later stage of this litigation. *See e.g., Williams v. Lederle Laboratories*, 591 F. Supp. 381, 386 (S.D. Ohio 1984).The only question at issue here is whether the Remicade label warned on NILD as a matter of law, and I find that it did not.

Conclusion

For the foregoing reasons, it is hereby

ORDERED THAT Defendant's motion for summary judgment is denied.

So ordered.

s/James G. Carr

U.S. District Judge